

REMARKS

Claims 1 to 10 have been cancelled. Claims 11-38 are still pending, and new claim 39 has been added. Of these, claims 11, 16, 25 and 39 are independent apparatus claims and claim 35 is an independent method claim.

Claim Rejections 35 USC § 103

The Examiner has rejected claims 11-34 under U.S.C. § 103(a) as being unpatenable over Kamen et al. U.S. Patent 5,628,908 (Kamen '908) in view of Dennehey et al. U.S. Patent 5,462,416 (Dennehey '416). The Examiner has also rejected claims 35-38 under U.S.C. § 103(a) as being unpatenable over Kamen et al. U.S. Patent 5,628,908 (Kamen '908) in view of Dennehey et al. U.S. Patent 5,462,416 (Dennehey '416) in further view Brierton et al U.S Patent No. 5,795,317.

The Kamen Reference

Independent claims 11, 16, 25, and 35 have been amended to overcome these rejections. Particularly, independent claims 11, 16, 25 and 35 have been amended to reflect a pump stations in selective communication with at least two fluid flow paths, and another pump station in selective communication with the same fluid flow paths.

This configuration is never present in Kamen. For instance, in Kamen, fluid paths F6 and F8 are associated only with pump chamber **P1**, while fluid paths F7 and F9 are associated only with pump chamber **P2** (see Col. 8, lines 15-22). In contrast, the pump chamber **P1** of Kamen could not be associated with its fluid paths F7 and F9 (which fluid paths are dedicated to **P2**) without physical disconnection and reconnection. Likewise, the pump chamber **P2** of Kamen could not be associated with its fluid paths F6 and F8 (which fluid paths are dedicated to **P1**) without physical disconnection and reconnection.

Although Kamen does suggest that the number and arrangement of the paths and valves may vary (Col. 7, lines 4-8), nowhere does Kamen suggest the claimed modification, nor does Kamen suggest how to make the claimed modification, nor does Kamen suggest why to make the claimed modification, nor does Kamen suggest the desirability of making the specific combination of the present invention. "[T]o establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability

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of making the specific combination that was made by the applicant.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000). In fact, isolated fluid paths in Kamen ‘908 are purposefully arranged to isolate the patient’s peritoneal cavity from air that collects in pump chambers P1 and P2 and to transfer the air out of P1 and P2 (see Col. 9, line 59 to Col. 10, line 4). Therefore, a system permitting communication between any pump station and any fluid flow path would not meet the objectives of the Kamen ‘908 device. In summary, Kamen does not suggest the particular arrangement of the present invention, and instead only broadly states that modifications can be made.

Furthermore, the Examiner has not addressed that Kamen does not teach or suggest programmable pneumatically actuated valves in the fluid flow paths, which are configured to place a first pump station in communication with two fluid flow paths and a second pump station in communication with the same two flow paths, and in which a programmable pneumatic actuator selectively applies pneumatic force to the valves and pump stations in response to a control program to direct fluid flow through any selected pump station in either a forward direction between two valves, or a reverse direction between two valves, or an in out direction through a single valve. In Kamen, the valve stations V1 to V4 serve only the upper ports of the pump chambers P1 and P2. These valve stations, in turn, serve only the noncritical liquid paths F1 and F2, conveying fluid from the patient (*see, e.g.*, Column 10, lines 18 to 26). Likewise, the valve stations V5 to V10 serve only the lower ports of the pump chambers P1 and P2. These valve stations, in turn, serve only the critical liquid paths F3, F4, and F5, conveying fluid toward the patient (*see, e.g.*, Column, lines 44 to 52). The exclusivity of this arrangement in Kamen is underscored by the repeated use of the term “only.” Under control of the pneumatic actuator, the pump stations in Kamen accommodate only one-way flow, in from the noncritical paths and out through the critical paths. Neither the pump stations nor the pneumatic actuator in Kamen are configured to direct fluid flow through any selected pump station in either a forward direction between two valves, or a reverse direction between two valves, or an in-out direction through a single valve. Claim 11 defines a system that is structurally different than Kamen’s system, and which performs a function that Kamen’s system does not teach or suggest and is not inherently capable of performing.


Kamen also does not teach or suggest a programmable blood processing system or method, as defined in claims 16, 25, and 35, that includes a cassette containing first, second, and third preformed, pneumatically actuated pump stations, more than three preformed fluid flow paths, and

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more than three preformed, pneumatically actuated valves in the fluid flow paths, and in which a programmable pneumatic actuator selectively applies pneumatic force to the valves and pump stations in response to a control program to place the first pump station in flow communication with any fluid flow path and the second pump station in flow communication with any fluid flow path, to simultaneously place two of the pump stations in flow communication with the blood separation device, while further simultaneously placing the third pump station in flow communication with a venipuncture. Kamen discloses a cassette with two pump stations for exchanging peritoneal dialysis solution. Kamen does not teach or suggest a blood processing system coupled to a blood separation device that includes a cassette to direct blood through three pneumatically actuated pump stations, more than three preformed fluid flow paths, and more than three preformed, pneumatically actuated valves, and in which a programmable pneumatic actuator selectively applies pneumatic force to simultaneously place two of the pump stations in flow communication with the blood separation device, while simultaneously placing the third pump station in flow communication with a venipuncture. Claims 16 and 25 define a system that is structurally different than Kamen's system. These claims and method claim 35 define functions that are different than the functions that Kamen's system performs, and which Kamen's system is not inherently capable of performing.

The Dennehey-Brierton References

In Dennehey '416 and Brierton '317, blood processing systems are disclosed, but there are no preformed, pneumatically actuated pump stations, and there is no motivation in these documents leading one to substantially redesign the cassettes of Dennehey or Brierton by removal of the peristaltic tube loops and their replacement with preformed, pneumatically actuated pump stations. The Examiner has indicated that Kamen contemplated other pumping means in the development of his invention because Kamen states that pneumatically actuated pumping action is only a preferred embodiment. However, nowhere does Kamen suggest other pumping means. Therefore, it is inappropriate to combine the pneumatic pumping teachings of Kamen with the peristaltic pumping teachings of Dennehey and Brierton. To modify the peristaltic pumping teachings of Dennehey and Brierton for a pneumatic system of Kamen would require a substantially redesign the cassettes of Dennehey or Brierton, removal of the peristaltic tube loops and their replacement with preformed, pneumatically actuated pump stations. None of the references suggest making the modifications as the Examiner has made.

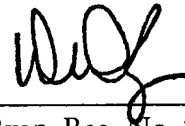


Furthermore, neither Dennehey (nor Brierton) discloses a programmable pneumatic actuator selectively applies pneumatic force to the valves and pump stations in response to a control program to direct fluid flow through any selected pump station in either a forward direction between two valves, or a reverse direction between two valves, or an in-out direction through a single valve. In fact, such an arrangement would not work with a peristaltic type pumping means. Particularly, or an in-out direction through a single valve is never disclosed in any of the references cited, and as such this element is wholly absent from the cited art, and such a reference surely would not come from a peristaltic disclosure.

Allowance of claims 11-39 is respectfully requested.

Respectfully Submitted,

By



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2 February, 2004

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